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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/767,138 | 01/23/2001 | Marc Alizon | 2356.0010-04 | 2082 |

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| EXAMINER | |
|---|---|
| PARKIN, JEFFREY S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/767,138 | ALIZON ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey S. Parkin, Ph.D. | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *23-64* is/are pending in the application.

4a) Of the above claim(s) *23-34 and 41-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *07/038,332* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## Detailed Office Action

### *Status of the Claims*

1. Applicants' election with traverse of Group III (claims 35-40) in paper no. 9 is acknowledged. The traversal is based upon the premise that it would not constitute an undue burden to search all of the claimed inventions concomitantly. Applicants argue that the claimed inventions all fall within the same class/subclass or are closely related. These arguments are not found persuasive for the reasons of record clearly set forth in paper no. 8. Applicants are reminded that establishment of *prima facie* evidence for a serious burden requires the demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02. The following items adduce a p*rima facie* showing of burden: 1) The inventions of Groups I-III/IV/V display both separate classifications and a separate status in the art as set forth in the last Office action. 2) The inventions of Groups I-IV are all directed towards independent and distinct subject matter. This was clearly explained in paper no. 8 as follows:

> 2. The inventions are distinct, each from the other because of the following reasons:
>
> 3. Inventions I-V are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, **each of the identified groups is directed toward a different product (e.g., HIV-1 virus with modified Gag, Pol, or Env, HIV-1 polypeptides, and nucleic acids encoding said polypeptides) with disparate structures, functions, chemical/physical/immunological/virological properties, and uses. Moreover, each group will clearly require separate searches.** Therefore, each group is clearly drawn toward a different inventive concept.

> Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Accordingly, each invention will generate unique issues regarding novelty, patentability, and enablement. 3) Since the inventions disclosed *supra* are directed towards patentably distinct material, a search for one invention would not necessarily result in the identification of art that is concomitant with that required to address the issues generated by the other inventions. Accordingly, **the requirement is still deemed to be proper and is therefore made FINAL.** Claims 23-34 and 41-64 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

### *Information Disclosure Statement*

2. The information disclosure statement filed 18 May, 2001, has been placed in the application file and the information referred to therein has been considered.

3. Applicants are reminded that the listing of references in the specification is not a proper information disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and M.P.E.P. § 609 ¶ A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited or considered by the examiner on a form PTO-892 or PTO-1449, they have not been considered.

### *35 U.S.C. § 112, First Paragraph*

4. The following is a quotation of the first paragraph of 35 U.S.C.

§ 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 35-40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims recite are directed toward HIV-$1_{ELI}$ envelope variants that differ from a number of prototypical HIV-1 isolates (e.g., IIIB, BRU, or ARV-2) by **one, three, five,** or **seven** amino acid residues. The disclosure describes the isolation and molecular cloning of a novel HIV-1 retrovirus designated ELI. However, the disclosure fails to identify any particular isolate that differs by the claimed number of amino acids. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

6. Claims 35-40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claimed invention is directed toward HIV-$1_{ELI}$ envelope variants that differ in at least one, three, five, or seven amino acid residues

from a number of other prototypical HIV-1 isolates (e.g., IIIB, BRU, or ARV-2). The disclosure describes the isolation, cloning, and characterization of a novel HIV-1 isolate designated HIV-$1_{ELI}$. Thus, the skilled artisan would reasonably conclude that applicants were in possession of this particular isolate. The disclosure does not describe the isolation and characterization of any other ELI variants, particularly those with the recited genetic variation. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of other ELI variants at the time of filing.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of HIV-$1_{ELI}$ envelope variants. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d

781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written

description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

As noted *supra*, the disclosure fails to provide a partial or complete nucleotide sequence of any HIV-$1_{ELI}$ envelope variant having the recited properties. While the disclosure provides the complete nucleotide and amino acid sequence of a single isolate, it fails to provide any data from any other variant. Moreover, considering the quasispecies nature of HIV-1, it would be extremely difficult for the skilled artisan to envisage any particular structure for any given variant. In fact, the skilled artisan could not reasonably predict what the final structure of any given variant would be. Applicants have provided a single isolate and are now attempting to obtain protection for isolates they have neither isolated nor characterized, which is clearly inconsistent with the law. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

7. Claims 35-40 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. As noted *supra*, the claims are directed toward HIV-$1_{ELI}$ envelope variants that differ by

one, three, five, or seven amino acids from known prototypical HIV-1 isolates (e.g., IIIB, BRU, or ARV-2). The disclosure describes the isolation and molecular cloning of a novel HIV-1 isolate designated ELI. Appropriately drafted claim language directed toward this embodiment would obviate the rejection. The disclosure does not detail the preparation and characterization of any other ELI variants. The disclosure also fails to identify the molecular determinants of the envelope that are essential for maintaining the integrity of the envelope and virion.

The legal considerations that govern enablement determinations pertaining to undue experimentation are disclosed in *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988) and *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows: 1) The disclosure fails to provide adequate guidance pertaining to the molecular determinants modulating ELI envelope structure. It is well-known in the art that retroviral envelope glycoproteins are large complex molecules. The HIV-1 envelope glycoprotein consists of a large 160 kDa glycoprotein that is cleaved into a surface form (gp120) and transmembrane form (gp41). In order to produce viable mutants the skilled artisan would require a knowledge of those portions of the envelope that can be modified without affecting the structural integrity of the envelope. However, the specification is silent concerning this point.

2) The claims are of considerable breadth and fail to receive adequate support in the specification. The claims potentially encompass a large number of variants that could include single or multiple amino acid additions, deletions, or substitutions. However, the disclosure fails to provide any guidance pertaining to those portions of the envelope that can be modified without affecting the normal function of the envelope.

3) The prior art is unpredictable and teaches that single or multiple amino acid additions, deletions, or substitutions can affect the function of any given biomolecule in an unpredictable manner. The disclosure fails to provide adequate guidance pertaining to this point.

4) The disclosure fails to provide suitable working embodiments. The claims encompass a large genus of viruses, however, there is nothing in the disclosure to suggest that other variants having the recited properties have been isolated and characterized. Thus, the disclosure fails to provide a suitable number of working examples. Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

## *Correspondence*

8. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

9. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

10. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

23 February, 2003